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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/988,013

11/16/2001

Shui-on Leung

18733/1082

7681

22428

7590

06/22/2006

FOLEY AND LARDNER LLP
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EXAMINER

BLANCHARD, DAVID J

ART UNIT

PAPER NUMBER

1643

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/988,013

Applicant(s)

LEUNG ET AL.

Examiner

David J. Blanchard

Art Unit

1643

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 June 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☒ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 28-32.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.


SHEELA HUFF
PRIMARY EXAMINER

Continuation of 3. NOTE: The reply filed 6/2/06 amends the claims to recite that the frameworks are selected from two or more human antibodies and the heavy chain framework regions have a sequence identity of at least 62.5% or higher and the framework regions of the light chain have a sequence identity of at least 69% or higher to the corresponding framework regions in the monoclonal antibody. Thus entry of the amendment would raise new issues, which require further consideration and search and new grounds of rejections. For example, the amendment filed 6/2/06 introduces new matter into the claims. The response states that support for the selection of framework regions from two or more human antibodies is found in Example 1 and Figure 1. This has been fully considered but is not found persuasive. As stated in the previous office action the REI framework region was selected for the light chain and the human EU framework region was selected for the heavy chain with the exception that human NEWM was selected for framework region 4, which is insufficient written support for the broader scope of the claims, which encompass selection of all four framework regions of both heavy and light chain variable domains selected from different human antibodies. Further, the selection of the NEWM FR4 of the heavy chain was due to lack of X-ray coordinate data for the EU sequence (see paragraph [0043], lines 11-16). Applicant states that the office action mailed 4/4/06 acknowledges that the present application supports the presently amended framework sequence identities (citing pg. 6, lines 17-19 of the office action mailed 4/4/06). Applicant is advised that it is not stated anywhere in the office action mailed 4/4/06 that the present application supports the framework sequence identity ranges as presently amended. Where at pg. 6, lines 17-19 does it state that there is adequate written support for the selection of heavy chain frameworks having a sequence identity of 62.5% or higher and selection of light chain frameworks having a sequence identity of 69% or higher? The framework residue identities pointed out by the examiner in the previous office action at pg. 6, lines 17-19 were to show that the present application did not provide adequate written support for the previously presented framework sequence identity range of 75%-92.3%. This was in no way intended to be construed as an invitation for any amendment, nor was it an acknowledgement that the present application provides adequate written support for the broader range of at least 62.5% or higher and at least 69% or higher. Where in the as filed disclosure is it contemplated that the frameworks are selected based on the recited sequence identities, i.e., heavy chain framework regions having a sequence identity of at least 62.5% or higher and light chain framework regions having a sequence identity of at least 69% or higher? Applicant can obviate a new matter rejection by providing sufficient written support for the limitations recited in the presently amended claims in the specification or claims, as-filed, or remove these limitations from the claims.

Continuation of 5. Applicant's reply has overcome the following rejection(s): If, if, if entered, the reply filed 6/2/06 would overcome the rejection of claims 28-32 under 35 U.S.C. 112, second paragraph as being indefinite.

Respectfully,
David J. Blanchard
571-272-0827

